

REMARKS

Claim Status

Claims 1-24 are pending.

Claims 3, 7 and 18 have been withdrawn in view of a restriction requirement.

Accordingly, claims 1, 2, 4-6, 8-17 and 19-24 are at issue.

Objections to the Specification and Claims

i.

Claim 1 has been amended to remove the part of chemical formula (A1). Thus, the claim should no longer be objectionable on that basis.

ii.

Objection has been made to the specification based on the new paragraphs added on page 4, after line 22, by the December 22, 2009 amendment herein.

Objection has similarly been made to claims 1-2, 4-6, 8-17 and 19-24 based on language added to claim 1 (specifying that the "hydroxyl protective group" is "*selected from ethers, esters, cyclic acetals and ketals, and cyclic ortho esters*") which is based on the added paragraphs.

For at least the reasons detailed herein, Applicant respectfully asserts that this objected to language does not constitute new matter, and that these objections should therefore be withdrawn.

Specifically, it is respectfully asserted that the reference to the TW Green book, where support for this language can be found, was present in the original specification by virtue of having been adequately incorporated by reference therein.

Applicant's arguments in support of this conclusion are submitted to be correct. Moreover, Applicant has supplemented its arguments with two Declarations submitted herewith.

FIRST, submitted herewith is the **Declaration of Santiago Jorda Petersen**, who is a Spanish IP attorney with extensive experience in the drafting and prosecution of patents for Spanish applicants in Spain and/or Europe and corresponding applications in other countries. (Petersen Declaration, ¶1). It is of no small significance that the present U.S. National Stage application is an English language translation National Stage application based upon a Spanish language PCT application claiming priority in a Spanish language application in Spain.

Thus, the claims in this U.S. application find their priority in the Spanish language applications filed in Spain, both as a national application and a PCT application, where it should be appreciated that their rules, not U.S. rules, apply. There, it is the practice not to use the "incorporated by reference" magic words in the disclosure because not only are they not required, but they are expressly prohibited in the EPO where many Spanish applications are subsequently filed. (Petersen Declaration, ¶¶2-6). In fact, there is a corresponding EPO application in which reference was made to the TW Green book in the Spanish language equivalent of the language used in the present application (*i.e.*, without, of course, use of the phrase "incorporated by reference"), and no such issue arose during that prosecution (Petersen Declaration, ¶7).

Moreover, in the expert and informed opinion of Mr. Petersen, each of the various corresponding applications (including this U.S. application) have clearly and sufficiently referred to the list of hydroxyl protective groups cited in the TW Green book (Petersen Declaration, ¶8). Further, use of the phrase "incorporated by reference", which the U.S. considers to be, in effect, "magic words", is disapproved and ineffective in the priority applications, and instead what was done in those priority applications was to use appropriate language in those countries to convey the intent that the hydroxyl protective groups cited in the TW Green book should be considered to be incorporated as a part of their disclosure (Petersen Declaration, ¶¶9-10). Any requirement to the contrary would place foreign applicants in an untenable Catch-22 situation – requiring either that they use language in foreign patent application(s) which those patent offices do not want used, or that they dishonestly "translate" the original non-U.S. application for the U.S. PTO to indicate use of language not actually included in the original foreign application(s).

In short, legally and logically, the reference to the TW Green book in the present U.S. National Stage application should be recognized as being sufficient to "[e]xpress a clear intent to incorporate by reference", 37 C.F.R. 1.57(b)(1), even though the root words "incorporat(e)" and "reference" were not used. As stated in 37 C.F.R. 1.57(g)(1), "[a] correction to comply with [37 C.F.R. 1.57(b)(1)] is permitted only if the application as filed clearly conveys an intent to incorporate the material by reference."

The present application does not have "[a] mere reference to material [which] does not convey an intent to incorporate the material by reference." 37 C.F.R. 1.57(g)(1). Thus, incorporation is appropriate. Applicant has elected to address the

concerns in the prior Office Actions by moving the entirety of the incorporated language into the specification (*i.e.*, by amending the application to include the complete list of hydroxyl protective groups). If preferred by the Examiner, Applicant is amenable to just changing the language to that preferred by U.S. practices, that is, by adding the phrase "incorporated by reference". In either event, it is respectfully submitted that the claims are supported, and no new matter is added.

SECOND, submitted herewith is the **Declaration of Angel Ramon Messeguer Peypoch**, who is an internationally known PhD organic chemist with numerous publications and extensive experience relating to bioactive organic compounds, and their methods of preparation, characterization and activity (Peypoch Declaration, ¶1). Dr. Peypoch has reviewed the priority Spanish language applications, this U.S. application, and the TW Green book (Peypoch Declaration, ¶¶2-3b, 5), and states that in his opinion:

- (a) the identification of the TW Green book in the patent applications is sufficient for him to be able to identify and obtain the book (Peypoch Declaration, ¶4);
- (b) the patent applications' references to "any of the hydroxyl protective groups of those described in" the TW Green book:
 - (i) refer specifically to the hydroxyl protective groups listed on pages 10-14 of the TW Green book (Peypoch Declaration, ¶5.a.i),
 - (ii) clearly convey that the specific hydroxyl protective groups listed on pages 10-14 of the TW Green book were intended to be incorporated as a part of the disclosure of the patent applications,

particularly that the listed groups were the full and complete list of such groups from which "R" in formulas (A1), (A2) and (A3) could be selected (Peypoch Declaration, ¶¶5.a.ii.), and

- (iii) are completely and accurately listed in the amendment to the specification in Corrected Amendment "B"(Peypoch Declaration, ¶¶5.a.iii.); and
- (c) *those of ordinary skill* in the art of chemistry and the technology of the present patent application would also understand the references in the patent applications to the TW Green book as he has, that is:
 - (i) the identification of the TW Green book in the patent applications should also be sufficient for anyone of ordinary skill in the art of chemistry to be able to identify and obtain the book (Peypoch Declaration, ¶4);
 - (ii) the patent applications' references to "any of the hydroxyl protective groups of those described in" the TW Green book:
 - (a) refer specifically to the hydroxyl protective groups listed on pages 10-14 of the TW Green book (Peypoch Declaration, ¶5.b.i),
 - (b) clearly convey that the specific hydroxyl protective groups listed on pages 10-14 of the TW Green book were intended to be incorporated as a part of the disclosure of the patent applications, particularly that the listed groups were the full and complete list of such groups from which "R" in formulas

(A1), (A2) and (A3) could be selected (Peypoch Declaration, ¶¶5.b.ii.), and

- (c) are completely and accurately listed in the amendment to the specification in Corrected Amendment "B"(Peypoch Declaration, ¶¶5.b.iii.).

In short, Dr. Peypoch's Declaration clearly supports the factual conclusion, consistent with the logical legal support provided by Mr. Petersen's Declaration, that the amendment to the specification merely adds exactly what was incorporated by reference in the original application(s), and thus that amendment cannot and does not constitute new matter. Correspondingly, claim 1 is similarly definite under 35 U.S.C. 112 in its recitation of the "hydroxyl protective group".

Claim Rejections

i.

Applicant gratefully acknowledges the withdrawal of the 35 U.S.C. §112, second paragraph rejection of claims 1, 2, 4-6, 8-17, 19-21 and 23-24 "due to the modification made in the claims".

Since the modification made in the claim 1 to address the 35 U.S.C. §112, second paragraph rejection was the added language which was objected to as discussed above, it is unclear whether or not this 35 U.S.C. §112, second paragraph rejection would return if that language were removed. If that is not the case, that is, *if claim 1 would be accepted under 35 U.S.C. §112 by deleting the added language, Applicant is agreeable to doing so to place the application in condition for allowance.*

As previously indicated, it is respectfully submitted that those skilled in the art would understand the meaning of "hydroxyl protective group" as originally used in claim 1 without the added language.

If the Examiner alternatively believes that the added language to claim 1 is necessary, it is respectfully submitted that the language is appropriate, and does not constitute new matter, for the reasons detailed above.

ii.

Claim 22 stands rejected under 35 U.S.C. §112, second paragraph because the phrase "formula (I) is obtained from formula (VI)" is said to be vague because it is not clear how formula (I) is obtained.

Claim 22 has been amended herein to specify that formula (I) is obtained from formula (VI) "by reacting said compound of formula (VI) with a haloform selected from chloroform, bromoform and iodoform, in the presence of a divalent chromium (Cr^{2+}) salt or complex". Thus, claim 22 is now considered to be definite and allowable under 35 U.S.C. §112.

Moreover, it is respectfully submitted that the addition to claim 22 is not new matter. Support for the added language is found at page 6, lines 1-11 of the application.

iii.

Only claims 22-24 have been rejected based on the prior art, that is, rejected under 35 U.S.C. §102(b) as anticipated by both Choudhry *et al.* (J. Org. Chem., 1993, 58, p. 1496-1500) and Deluca *et al.* U.S. Patent No. 4,847,012.

It is respectfully submitted that whatever correspondence may be alleged to be found between the disclosure of Choudhry *et al.* or Deluca *et al.* and the formula in claims 22-24, claims 22-24 depend from claim 1, and whatever is taught in either reference neither shows nor suggests a compound having the structure as recited by claim 1 together with claims 22-24.

Accordingly, claims 22-24 are respectfully submitted to be allowable.

In view of the above, claims 1-24 are now submitted to be in condition for allowance. Early notification to that effect is respectfully requested.

Respectfully submitted,

WOOD, PHILLIPS, KATZ,
CLARK & MORTIMER

By _____
Jeffrey L. Clark
Reg. No. 29,141

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500 West Madison Street
Suite 3800
Chicago, IL 60661
(312) 876-2111